U. S. Department of Energy

Consolidated Audit Program

Module 6

Hazardous and Radioactive Materials Management

Revision 2
February 17, 2004

Audit ID:

ITEM	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
6.1	**Standard Operating Procedures/Waste Management Plan**		
6.1.1	The laboratory demonstrates compliance or exempt status with the environmental, safety and health requirements of applicable laws, regulations, and standards *(Quality Systems for Analytical Services Section on Environment Health and Safety*)		
6.1.2	The laboratory has a waste management plan in place which is capable of: • identifying all waste streams generated by the laboratory; • identifying the process for managing and disposition of the various waste streams; and, • tracking the disposition of waste sample by Sample Data Group (SDG) includes universal wastes such as batteries, thermostats, etc. (*Quality Systems for Analytical Services Section on Environment Health and Safety*)		

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6.1.3	The waste management plan shall include (not limited to) the following: • administrative programs to demonstrate compliance for effluent discharges as required by regulatory agencies; • training procedures, schedules and management of training records in the areas of waste management, shipping, waste handling and radioactive materials control; • radioactive volumetric and surface release policies; • permits and licenses to handle hazardous and radioactive waste; • policy or direction on how to conduct waste brokering and Transport, Storage and Disposal Facility (TSDF) evaluation to ensure proper disposition of waste; • tracking of individual sample containers from receipt to final disposition • waste minimization program including substitution (when permitted), segregation, recycling, etc. (*Quality Systems for Analytical Services Section on Environment Health and Safety*)		
6.2	**Radioactive Materials Management and Control**		
6.2.1	The laboratory has in place a radioactive materials inventory program capable of tracking standards, tracers and all licensable samples (*Quality Systems for Analytical Services Section on Environment Health and Safety*)		

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6.2.2	Qualifications requirements for the RSO have been defined.		
6.2.3	An onsite person is present to fill the function of RSO and this person is listed in the Radioactive Materials License. *(Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.4	The radioactive materials license allows possession of sufficient quantities of radioactive samples to meet DOE specific contract needs. The license includes materials which include materials likely to be sent to the laboratory which reflect radioactive contaminants of concern for DOE sites. *(Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.5	The laboratory reviews at least annually the radiation protection program content and implementation as required by 10 CFR 20.1101, and records of audits, reviews, and inspections over the last 3 years are kept on file. *Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.6	A survey or monitoring program is in place to assess the extent of potential radiological hazards. *(10 CFR 20.1501(a))* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.2.7	The laboratory monitors worker external exposure for those employees likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the limits in 10 CFR 20.1201(a). Ask the RSO to walk you through their process. *[10 CFR 20.1502(a)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.8	The laboratory monitors worker internal exposure of those employees likely to receive, in 1 year, an intake in excess of 10% of the applicable Annual Limit(s) on Intake [ALI(s)] *(10 CFR 20.1502(b))* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.9	The total effective dose equivalents (TEDE) and total organ dose equivalents (TODEs) are within limits i.e. summing internal and external dose. *(10 CFR 20.1201 and 1202)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.10	All individuals in or frequenting any portion of a restricted area are instructed in the health protection problems associated with exposure to radioactive materials or radiation, precautions/procedures to minimize exposure, and the purpose and functions of protective devices employed *[10 CFR 19.12(a)(2)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.2.11	Workers demonstrated understanding of radiological controls, radioactive material handling procedures, emergency procedures, and use of instrumentation. *[10 CFR 19.12, 20.1101(a)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.12	Licensed material is secure from unauthorized access or removal *(10 CFR 20.1801, 1802)* *(Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.13	Personnel dealing with radioactive waste management and materials shipping are trained in waste management, shipping and handling, and radioactive material control. *(Analytical Support Agreement, 49 CFR 172 Subpart H)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.14	Appropriate, operable/calibrated survey instrumentation is readily accessible. *[10 CFR 20.1501(b)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.2.15	Instrument and equipment calibration records for radiation survey instruments are maintained. *[10 CFR 20.2103(a)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.16	Airborne releases of radioactivity to the environment are monitored, evaluated, and controlled. *[10 CFR 20.1301(a)(1), 1501(a) and 1701, EPA NESHAPS]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.17	The effluent released to the sanitary sewer meets four provisions of 10 CFR 20.2003 (i.e., readily soluble, quantity released into sewer does not exceed concentration listed in appendix B to Part 20, determination of fractional limits and sum of those fractions for each radionuclide). *(10 CFR 20.2003)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.18	Waste packaging, control, and tracking is performed in accordance with Appendix F III requirements i.e., classification, labeling, QC program, and preparing, forwarding manifests. *[10 CFR 20.2006(d)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.2.19	Disposed sample container "radioactive" labels are removed or defaced. *[10 CFR 20.1904(b)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety 11.5)*		
6.2.20	The facility's documented "No Rad Added" policy is implemented (i.e., established radioactive volumetric and surface release policies). *(DOE Contractual Requirement)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.21	Waste shipments are transferred to qualified facility/person specifically licensed to receive waste. *[DOE Contractual Requirement, 10 CFR 30.41, 20.2001(b)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.22	Records of waste disposal are maintained. *(10 CFR 20.2108)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.2.23	Areas of radioactive material handling and contamination are posted according to 10 CFR 20.1902 and 1904. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.2.24	At sample receiving, samples from potentially radioactive sites are screened to ensure that customer identification of radioactivity (or lack of radioactivity) is correct, to ensure that sample is properly categorized (per their definition of radioactivity) for sample handling in the laboratory, and, in the absence of customer supplied information, to obtain data input for the radioactive materials license tracking system. Screening should ensure that the shipping container does not exhibit loose contamination or unacceptable external radiation readings. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3	**Analytical Process Waste and Excess Sample Material**		
6.3.1	The laboratory has procedures in place to minimize analytical process waste. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.2	Analytical process waste is segregated and removed to an appropriate storage area as soon as practical in order to minimize the potential for cross contamination. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.3.3	Laboratory characterizes each analysis derived waste stream for hazardous waste characteristics (RCRA), TSCA regulated levels, and radioactivity. Characterization can be performed either by testing and/or documented process knowledge. *[40 CFR 262.11(c)(1),(2) and 262.40, 10 CFR 20, 40 CFR part 761]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.4	Characterization records include analytical test results and process knowledge determinations and are kept for at least 3 years. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.5	Laboratory analysis derived waste characterization is repeated at a frequency adequate to account for all known variations in the waste streams. *[40 CFR 262.11(c)(1),(2) and 262.40, 10 CFR 20, 40 CFR part 761]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.6	Laboratories are accumulating no more than 55 gal of hazardous and mixed waste or no more than 1 qt of acutely hazardous waste at or near any point of generation (satellite point). (40 CFR part 262) (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.3.7	For RCRA wastes, containers are in good condition; compatible with the waste, kept closed and marked with the words "HAZARDOUS WASTE" or other words identifying contents. *[40 CFR 262.34(c)(1)(i),(ii) and 265.171, 172, and 173(a)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.8	Wastes from samples containing PCBs at greater than 50 ppm is segregated from other lab wastes as TSCA regulated waste. (NOTE: This does not apply to the extracted sample residual BUT it does apply to the extract and other lab process wastes). *(40 CFR part 761)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.9	Lab generated TSCA wastes are not stored in a Temporary Storage area more than 30 days from the time of generation without being placed in an area that meet one year storage facility requirements. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.10	TSCA waste containers and sample storage areas are marked with the required TSCA labeling as identified in 40 CFR 761.40 and 45. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.3.11	Radioactive and mixed wastes generated during laboratory sample processing are properly labeled as Radioactive. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.12	Radioactive and mixed wastes are segregated from non-radioactive process wastes. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.13	Staff is trained in housekeeping practices acceptable the in laboratory waste storage areas with no spilling or exposure hazards present. (OSHA, RCRA) (*Quality Systems for Analytical Services 7.2 c & d)*		
6.3.14	Laboratory waste that is drain disposed is approved by the receiving POTW or site treatment facility. *(CWA)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.15	Incompatible wastes are not mixed together or water reactive wastes are not drain disposed. *(OSHA)* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.3.16	If required by contract, the laboratory has provisions for the return of excess sample material to the client's custody. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.17	The laboratory has provisions for disposal of excess samples, if required by the contract. (*Quality Systems for Analytical Services 11.8 & 12.4.5)*		
6.3.18	A system exists that provides for cradle to grave tracking of excess samples. (*Quality Systems for Analytical Services 12.4)*		
6.3.19	The sample tracking system documents the eventual fate of samples including those consumed during analysis, drain disposed, long term archival, or returned to the customer. (*Quality Systems for Analytical Services 12.4)*		
6.3.20	For drain and drum disposed samples, the sample tracking system documents the date of sample disposal and the drum number, as applicable. (*Quality Systems for Analytical Services 12.4)*		

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6.3.21	For excess samples that are bulked and drain disposed, the laboratory is aware of the requirements for the receiving wastewater treatment system and has a program that meets and demonstrates compliance with these requirements. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.3.22	For excess samples that are bulked and disposed as solid wastes, the laboratory has a testing program to ensure that the waste is adequately characterized prior to manifesting to an offsite disposal facility. This testing program: • is repeated at adequate periodicity; and, • includes all potential radioactive and hazardous components. (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.4	**Waste Storage Areas**		
6.4.1	PCB (TSCA) waste is not stored for more than 1 year from the date the material was first placed in storage. *[40 CFR 761.65(a)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.4.2	TSCA one year waste storage area meets the storage facility requirements for PCB waste. *[40 CFR 761.65(b)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.4.4	For RCRA Large Quantity Generators: No waste containers are stored over 90 days in the accumulation/storage area. *[40 CFR 262.34(a),(b)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.4.5	For RCRA Small Quantity Generators: No waste containers are stored over 180 days (270 days if transported over 200 miles) in the accumulation/storage area of a Small Quantity Generator. *[40 CFR 262.34(d),(e)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.4.6	For RCRA Small and Large Quantity Generators: Containers are in good condition, compatible with the waste, kept closed and inspected at least weekly. *[40 CFR 262.34(a)(1)(I) and 265.171, 172, 173, and 174]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		

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6.4.7	For RCRA Small and Large Quantity Generators: Incompatible waste stored near other containers is separated by a dike, berm, wall, or other device. *[40 CFR 265.177(c)]* (*Quality Systems for Analytical Services Section on Environment Health and Safety)*		
6.5	**Waste Container Management**		
6.5.1	Satellite accumulation containers are labeled with accumulation start dates. *[40 CFR 262.34 (a) (3)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.2	Satellite accumulation containers are labeled with the words “Hazardous Waste” or other words that clearly define the contents. *[40 CFR 262.34 (c)(ii)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.3	Satellite accumulation containers are routinely checked to make sure that no one container has accumulated more than 55 gallons of waste. *[40 CFR 262.34 (c)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.5.4	Satellite accumulation containers are routinely checked to make sure that no one container has accumulated more than one quart of acutely hazardous waste. *[40 CFR 262.34 (c)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.5	Satellite accumulation area, other waste areas, and containers of waste are being monitored weekly by an operator or someone knowledgeable in waste operations specific to this facility. *[40 CFR 262.34 (c) & 265.174]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.6	The user(s) or operator(s) of the satellite accumulation areas understand container/waste compatibility and have been trained with respect to container selection, waste identification, documentation, and management. *[40 CFR 265.172 & 177]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.7	Outgoing shipments of materials are in accordance with 49 CFR 172, 173, 178, and 179. *[40 CFR 262.31-32]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.5.8	A dike, berm, wall, or other device separates incompatible waste containers. *[40 CFR 265.177 (c)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.9	The waste storage area provides secondary containment of sufficient quantity for the waste expected to be stored in the areas. *[40 CFR 265.193]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.10	Ignitable and reactive waste is stored at least 50 feet from the property line. *[40 CFR 265.176]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.5.11	Accumulation containers used must meet the container requirements in 40 CFR Part 265, Subpart I. *[40 CFR 262.34 (a) (1) (I)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.6	**Laboratory Contingency Plan and Emergency Procedures**		
6.6.1	For RCRA Large Quantity Generators: The laboratory has a written contingency plan and a copy is available at the facility. *[40 CFR 262.34(a)(4), and 265.50, 53]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.2	For RCRA Small Quantity Generators: The following information is posted next to the phone in the vicinity of the accumulation area: name and number of the emergency coordinator, location of fire extinguishers and spill control material, and fire department number or a direct alarm. *[40 CFR 262.34(d)(5)(ii)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.3	For Large and Small Quantity Generators: Required equipment available at the accumulation/storage area i.e., internal communication or alarm system, telephone or hand-held two-way radio, portable fire extinguishers/fire control equipment, spill control equipment, and water at adequate volume and pressure (e.g.; 15 minutes of continuous pressure). *[40 CFR 262.34(a)(4) and (d)(4) and 265.32]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.6.4	The laboratory has formally designated an *Emergency Coordinator* that is on the premises or on call at all times. *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.5	While on call, the Emergency Coordinator can reach the facility in a short period of time (e.g.; 10-20 minutes). *[40 CFR Part 262]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.6	The Emergency Coordinator is qualified and trained in this capacity. *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.7	Facility has prepared a written emergency action plan to ensure employee safety from fire and other emergencies and employees have been trained on the plan [29 CFR 1910.38(a)(1) and (a)(5)]. *NOTE: This can be the same as the RCRA LQG required contingency plan HOWEVER the lab must ensure that the combined plan meets both OSHA and RCRA requirements.* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.6.8	Employer has ensured the ready availability of: • medical personnel for advice and consultation on matters of employee health; • an emergency eye wash within the immediate work area; and, • an emergency shower provided within the immediate work area. *[29 CFR 1910.151(a) and (c)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.9	Employer has provided, mounted, located, identified, and inspected portable fire extinguishers so that they are readily available to all employees without subjecting the employees to possible injury. *[29 CFR 1910.157(c)(1) and (e)(1)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.10	Employer has developed a spill control policy, as well as provided, located, and identified spill kits so that they are readily available to all employees. *[29 CFR 1910.1450 Appendix A]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.6.11	Facility is equipped with an alarm system which is capable of being detected and recognized by the employee in case of emergency *[29 CFR 1910.165(b)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.7	**Chemical Hygiene Plan**		
6.7.1	A chemical hygiene plan (CHP) has been developed and implemented in the laboratory and is readily available to the employees. *[29 CFR 1910.1450(e)]*		
6.7.2	Standard operating procedures (SOPs) relating to safety and health considerations have been developed and are being followed. *[29 CFR 1910.1450(e)(3)(I)]* *(Quality Systems for Analytical Services Section 5.2)*		
6.7.3	Initial and periodic exposure monitoring for hazardous chemicals has been conducted and exposures to Occupational Safety and Health Administration (OSHA)-regulated substances used in the laboratory do not exceed the permissible exposure limits specified in 29 CFR 1910, Subpart Z. *[29 CFR 1910.1450(c)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.7.4	Material Safety Data Sheets (MSDSs) are on file for all hazardous chemical substances maintained by the laboratory and are readily accessible to all employees. *[29 CFR 1910.1450(h)(ii)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.7.5	Measures are in place to ensure the performance and maintenance of ventilation hoods and protective equipment. *[29 CFR 1910.1450(e)(3)(iii)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.7.6	Laboratory analytical employees have been trained on: • contents of the employer's CHP; • physical and health hazards of chemicals in the work area; and, methods and observations used to detect the presence or release of a hazardous substance (e.g. Monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous substances being released). *[29 CFR 1910.1450(e)(4)and(f))]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.7.7	If respirators are used during sample or waste handling/processing, Laboratory has an appropriate written respiratory protection program, including: • SOPs governing the selection and use of respirators; and, • annual evaluation to ensure effectiveness. *[29 CFR 1910.134(a) and (b)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.7.8	Chemical hazard labeling on chemical containers is in accordance with the laboratory's approved Chemical Hygiene Plan *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.8	**Laboratory Facility Safety**		
6.8.1	Are exits identified and unobstructed. *[29 CFR 1910.36(d) and 37(a)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.8.2	A laboratory safety inspection program is in place that includes routine walkdowns of laboratory areas for safety related concerns. *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.8.3	Signs for safety showers, eyewash stations, other safety and first aid equipment, exits and areas where food and beverage consumption and storage are permitted available. *[29 CFR 1910.1450 Appendix A , (D) (8)(c)(24)(27)]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		

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6.8.4	Areas containing biological hazards are appropriately posted and contained. *[29 CFR 1910.1030]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.8.5	All hazardous or toxic chemical cabinets are appropriately labeled. *[29 CFR 1910.1200(f)(5) and 1450 Appendix A]* *(Quality Systems for Analytical Services Section of Environment Health and Safety)*		
6.9	**Sample Receiving**		
6.9.1	The laboratory has procedures in place to address the following: • checking sample preservation, i.e., pH; • proper containers; • preserving samples when required; • notifying clients of shipping or sample anomalies; • checking holding times and notification of lab personnel of short holding times; • use of fume hoods for opening samples and shipping containers; and, • radiation screening of samples, lab notification and labeling requirements for radioactive samples. *(Quality Systems for Analytical Services 11.2a, b, c, d and f; 11.3c)*		

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6.9.2	Sample custodians document anomalies encountered in the sample receiving process. *(Quality Systems for Analytical Services 11.3c)*		
6.10	**Sample Control and Building Security**		
6.10.1	Physical or administrative controls exist to ensure that: • chain of custody (COC) is not broken during times that laboratory staff are present or not present, • visitor access is controlled by positive administrative controls and strict escort rules developed for all visitors; and, • the facility has controlled entrance and egress point. *(Quality Systems for Analytical Services 12.0)*		
6.10.2	A sample receiving logbook or equivalent system is used to record the chronology of sample entry into the laboratory including time, date, customer, sample identification numbers, etc. *(Quality Systems for Analytical Services 11.3d)*		
6.10.3	When the laboratory receives samples, an internal chain of custody procedure is initiated. *(Quality Systems for Analytical Services 11.3f)*		

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6.10.4	Internal custody is maintained until final disposition or return of the sample to the client. *(Quality Systems for Analytical Services 11.3f)*		
6.10.5	The laboratory maintains an indexed sample storage system that facilitates sample retrieval. *(Quality Systems for Analytical Services 11.3f)*		
6.10.6	The laboratory has established, implemented and documented procedures to ensure the sample's radioactivity levels are consistent with the accompanying documentation and that laboratory regulatory levels are not exceeded. *(Quality Systems for Analytical Services 11.4c)*		